compared with Symbicort® Turbuhaler®was based on a conservative assumption. **RESULTS:** An estimated 167,666 adult patients used Symbicort® Turbuhaler® annually in Sweden and were therefore eligible for treatment with DuoResp® Spiromax®, with 72,935 of these exhibiting poor inhalation technique. Based on the predicted improvement in inhalation technique with DuoResp® Spiromax® compared with Symbicort® Turbuhaler® – and assuming a hypothetical uptake of DuoResp® Spiromax®reaching 25% in years 4 and 5 – estimated societal cost savings, through the avoidance of 147,158 lost productive days, totalled SEK285.4 million (€31.2 million). **CONCLUSIONS:** DuoResp® Spiromax® has the potential to improve inhalation technique compared with Symbicort® Turbuhaler®, which would likely result in substantial societal cost savings.

PRS63

IMPACT OF OMALIZUMAB ON ALL-CAUSE AND ASTHMA-RELATED HEALTH CARE RESOURCE UTILISATION IN PATIENTS WITH MODERATE OR SEVERE PERSISTENT ASTHMA

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OBJECTIVES: Increased health care resource utilisation (HCRU) is associated with inadequately controlled asthma. Here, we evaluate the impact of omalizumab on HCRU in patients with moderate or severe persistent asthma. **METHODS:** A retrospective case-crossover study was conducted using the Truven MarketScan database. Data between 1-January-2007 to 30-September-2012 was collected for analysis. Patients included in the analysis had to have a diagnosis of moderate or severe persistent asthma, be ≥12 years of age during the analysis period, have had 2 years of continuous enrolment (1 year pre/post omalizumab index date), and have had exposure to omalizumab continuously for ≥12 months. All-cause and asthma-related HCRU during the years, pre and post omalizumab initiation, were compared using McNemar tests and 2-sided paired Student's t test. Data were stratified by asthma severity based on NHLBI criteria. **RESULTS:** A total of 429 patients (mean age, 46.6 years; female, 59.0%; Moderate=340 [79.3%], Severe=89 [20.7%]) from the database were included in the analysis. The use of omalizumab was associated with 49.3% (p=0.0003), 54.0% (p=0.001), and 35.3% (p=0.1466) reductions in the mean number of asthma-related ER visits and 69.2% (p=0.0005), 65.5% (p=0.0045), and 80.0% (p=0.0449) reduction in the mean number of asthma-related hospitalisations among All, Moderate, and Severe asthma patients, respectively. The mean length of stay for asthma-related hospitalisations was also reduced to 71.2% (p=0.0002), 64.5% (p=0.0016), and 90.6% (p=0.0442) in All, Moderate, and Severe patients respectively. All-cause ER visits were reduced by 30.8% (p=0.0014), 32.5% (p=0.0045), and 25.0% (p=0.1348), and hospitalisation reduced by 48.9%, 45.2%, and 64.7% (all p≤0.0155) in All, Moderate, and Severe asthma patients respectively. Cohort analysis of severe asthmatics was limited by sample size. **CONCLUSIONS:** In patients with moderate persistent asthma, omalizumab use was associated with significant reductions in all-cause and asthma-related HCRU.

PRS64

DEVICE HANDLING ERRORS AND THE IMPACT ON QUALITY OF LIFE AND HEALTH CARE RESOURCE USE IN ASTHMATIC PATIENTS

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OBJECTIVES: Correct device technique has a significant influence on the delivery of inhaled therapies and can thus impact the control and management of asthma. The objective of this literature review was to examine the impact of device handling errors on QOL and health care resources to understand the potential value of a novel inhaler device for health care systems and patients. **METHODS:** A literature search of articles published 2009–2013 was undertaken using MeSH terms and key words in MEDLINE®, supplemented by a grey literature review and searching of reference lists. Article selection and relevant data extraction were based on key words relating to handling error, QOL, and health care resource use. **RESULTS:** Of 575 potentially relevant publications, 22 were selected for in-depth review. Papers reported 25–73% of patients make critical handling errors that lead to no-dose or reduced-dose delivery on first use of devices. Incorrect inhaler use was four times more frequently reported in patients with uncontrolled asthma than in patients with controlled asthma. Poor asthma control also impacts resource use: poorly-controlled patients made twice as many ER visits, and spent 2–3 times more time consulting with physicians than controlled patients (either physician visits or time speaking to physicians). Asthma control also impacts QOL: poorly-controlled patients reported health-state utility (EQ-5D) values of 0.52–0.69, compared to 0.88–0.93 for well-controlled patients. **CONCLUSIONS:** Handling errors with devices can lead to poorly-controlled patients, resulting in reduced QOL and increased health care resource use. New inhaler devices represent an opportunity to reduce errors and improve asthma control, therefore improving QOL and reducing resource use. Further research is required to model the relationship between a reduction in handling error and improved asthma control status, and the subsequent impact on resource use and QOL.

PRS65

MEDIUM TERM AVOIDED COSTS: HIGH-DOSE HYPOALLERGENIC HOUSE DUST MITE PREPARATION IMMUNOTHERAPY VERSUS CONVENTIONAL SYMPTOMATIC TREATMENT

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OBJECTIVES: Quantifying cost difference between conventional symptomatic treatment of mite allergy and subcutaneous specific immunotherapy (SCIT) with high doses of hypoallergenic dust-mite preparation. **METHODS:** Observational, retrospective and multicenter study carried out in Spain in 2013.419 patients diagnosed with rhinitis and / or bronchial asthma for mite allergy were retrieved. Mean age 24.9 years (SD 14.4). Comparing the use of symptomatic medication (rescue and daily), diagnostic-tests, unscheduled medical care (allergist and emergency visits) and sick-leave days number associated with SCIT treatment versus no SCIT treatment. SCIT treatment vs no SCIT treatment costs ratio was performed: Used resources (Symptomatic medication, unscheduled medical care, diagnostic-tests, and 3 years SCIT treatment and sick-leave days) were quantified in €. Efficacy (decreased resource usage) of first year treatment was assumed during the remaining two years and during a three years follow-up period. **RESULTS:** After a single year of SCIT all quantified resources (emergency and allergist visits, diagnostic tests, rescue medication and work absence days) diminished significantly (p<0.05) from baseline. Reductions in resources' cost: Hospital resources (100% in Hospitalizations; 82% in additional visits to the allergist; 79% in ER visits). In medication: (56% in rescue medication; 63% in daily medication). In diagnostic tests: (75% in spirometry testing broncho-dilation; 72% in O2 saturation measuring; 90% in FeNO measuring and 81% in chest radiographs. In leave sick days 94%. Ratio of comparative calculation described as SCIT treatment versus non SCIT treatment (or conventional symptomatic treatment) is 0.8. **CONCLUSIONS:** Considering 3 years of SCIT, and 3 follow up years of sustained efficacy after completing treatment, cost per patient SCIT treated is estimated at 20% below to the cost non SCIT treated patient. Direct costs are reduced by 64% and indirect costs by 94%. SCIT of hypoallergenic preparation of dust-mite allows cost savings vs conventional treatment.

RESPIRATORY-RELATED DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PRS66

ESTABLISHING THE RELATIONSHIP OF INHALER SATISFACTION, ADHERENCE, SMOKING HISTORY AND ALLERGIC RHINITIS WITH PATIENT OUTCOMES: REAL WORLD OBSERVATIONS IN US ADULT ASTHMA PATIENTS

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OBJECTIVES: Improving asthma control has more recently focused on potentially modifiable clinical and behavioural characteristics including correct inhaler technique, treatment of concomitant allergic rhinitis (AR), adherence and smoking. This research aimed to establish the relationship of these factors with measures of asthma control and overall health status to add to the growing body of evidence helping to optimize asthma management interventions. **METHODS:** Data were drawn from the USA 2013 Respiratory Disease Specific Programme, a cross-sectional survey of adult asthma patients consulting for routine care. Partial Least Squares Path Modelling was used to quantify the inner model relationships between latent variables of patient-reported satisfaction of drug delivery, device functionality, device feedback (based on groupings of 12 inhaler device attributes), concomitant AR, adherence (Morisky Medication Adherence Scale), smoking history (smoking status, years smoked, number smoked per day), patient reported outcomes (Asthma Control Test, Jenkins Sleep Questionnaire, EuroQol-5D-3L) and physician-reported number of asthma exacerbations in the last 12 months. Patients not receiving inhaled maintenance therapy were excluded. **RESULTS:** 243 patients met the inclusion criteria. All manifest variable loadings were positive, and a minimum Cronbach's Alpha of 0.713 for the latent variables indicated unidimensionality of the manifest variables for each of the latent variables. Cross-loadings were also supportive of the hypothesised outer model. Better patient outcomes were significantly associated with patient satisfaction with drug delivery (p=0.002), adherence (p=0.049), negative smoking history (p<0.001) and absence of concomitant AR (p=0.005). The R^2 value for outcomes was 13.3%, and the pseudo goodness of fit, which measures the overall prediction performance of the path model, was 19.5%. **CONCLUSIONS:** Improving patient satisfaction with inhaler drug delivery represents one potentially modifiable aspect of asthma management alongside appropriate treatment of AR, smoking cessation and improving adherence, which are likely to have a positive impact on asthma patient outcomes.

PRS67

TECEPOC II STUDY. HOW TO IMPROVE THE INHALATION TECHNIQUES IN PATIENT WITH COPD. THE INFLUENCE OF PREFERENCES

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OBJECTIVES: to test the efficacy of two educational interventions to improve the inhalation techniques in patients with Chronic Obstructive Pulmonary Disease and the influence of patient´ preference. **METHODS:** Design: Multicenter patients´ preference trial or comprehensive cohort design ISRCTN15106246. Patients: 465 COPD patients (to detect a difference between groups of 25%, 80% statistical power, 95% confidence level, 40% expected losses), with inhaled treatment, written consent. Non-probabilistic consecutive sampling. Allocation: Patients without strong preferences for a treatment were randomised: RCT group (block randomization), and those with strong preferences were given their choice: PPS group. Variables: *Primary outcomes*: Performance of correct inhalation technique. *Secondary outcomes*: Pick flow, Baseline dyspnea index (BDI), Functional status (forced spirometry). Interventions: *Intervention-A:* Written information. A leaflet with the correct inhalation technique for the main inhaler devices used in our area. *Intervention-B:* Intervention-A + individual training (by instructors). Follow-up: 12 month, visits: baseline, 1 month, 3rd month, 6th month, 12th month. Statiscal analysis: Mean, frequency, 95% confidence interval at baseline. Number Needed to Treat for a benefit (NNT) was calculated. Intention to treat analysis. **RESULTS:** Predominance of males (91.4%), mean age 69.8 years (CI95%, 69.00-70.59); FEV1 (mean)=55.91% (IC95%, 53.62-58.2), mixed respiratory pattern (65.9%). Severity stage: 15.7% mild, 44.1% Moderate, 40.3% Severe. Pharmacological treatment: inhaled-beta2-adrenergic (88.8%); inhaled-corticoster-

oids (76.7%); inhaled-anticholinergic (70.7%); mucolitycs (19.4%); xanthine (7.3%); oral-corticosteroids (1.3%). BDI: grade 2. Primary outcome: RCT cohorts: there was no difference between control and intervention A and there were statistically significative differences between intervention B versus control ($p<0.0001$), NNT=3.22 (IC95%, 2.27-5.88) and versus intervention A, NNT=4.16 (IC95%, 2.63-10). In the PPS cohorts: there was a difference ($p<0.0001$) between intervention B versus intervention A, NNT=3.22 (IC95%, 2.32-5.55). The preferences enhanced a 6.7% the correct inhalation technique. **CONCLUSIONS:** The performance of a correct inhalation Technique improves with monitor training. The patients´ preferences enhance the efficacy of intervention.

PRS68

INHALATION TECHNIQUE EVOLUTION AFTER TRAINING IN COPD. THE ROLE OF THE DEVICE

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OBJECTIVES: To test the efficacy of two educational interventions to improve the inhalation techniques per device in patients with COPD and the influence of patient´ preference. **METHODS:** Design: Multicenter patients´ preference trial or comprehensive cohort design ISRCTN15106246. Patients: 465 COPD patients (to detect a difference between groups of 25%, 80% statistical power, 95% confidence level, 40% expected losses), with inhaled treatment, written consent. Non-probabilistic consecutive sampling. Allocation: Patients without strong preferences for a treatment are randomised: RCT group (block randomization), and those with strong preferences are given their choice: PPS group. Variables: *Primary outcomes*: Performance of correct inhalation technique. *Independent variables:* sex, age, Baseline dyspnea index (BDI), Functional status (forced spirometry). Interventions: *Interv-A:* Written information. A leaflet with correct inhalation technique. *Interv-B:* Interv-A + individual training (by instructors). Follow-up: 3 month, visits: baseline (V0), 1 month (V1), 3 month (V2). Statiscal analysis: Mean, frequency, 95% confidence interval. Intention to treat analysis. **RESULTS:** Males (91.4%), mean age 69.8 years (CI95%, 69.00-70.59); FEV1 (mean)=55.91% (IC95%, 53.62-58.2), mixed respiratory pattern (65.9%). Severity stage: 15.7% mild, 44.1% Moderate, 40.3% Severe. BDI: grade 2. Devices use: 67.3% Handihaler (Hd), 54.8% Turbuhaler (Th), 31.8% Accuhaler (Acc), 26.9% pMDI. Correct Inhalation technique: **Hd:** RCT-control: 11.7% V0,10% (V2); RCT-intervA: 10.9%, 17.5%; RCT-IntervB: 7.4%, 62.3% $p< 0.0001$. **Th:** RCT-control: 22% V0, 16.7% (V2); RCT-intervA: 8.7%, 24.4%; RCT-IntervB: 7.5 %, 57.5% $p< 0.0001$. **Acc:** RCT-control: 16.1% V0, 25% (V2); RCT-intervA: 17.9%, 23.1%; RCT-IntervB: 11.5%, 74.1% $p< 0.0001$. **pMDI:** RCT-control: 6.9% V0, 3.6% (V2); RCT-intervA: 12.5%, 19%; RCT-IntervB: 8.3%, 34.6% $p=0.025$. There were statistically differences for all devices only in the intervention B arms ($p<0.0001$). The preferences enhanced 1% for Handihaler, 12.7% for Accuhaler, 4.6% for Turbuhaler, 15.4% for pMDI the correct inhalation technique. **CONCLUSIONS:** The performance of a correct inhalation technique improves with monitor training for all devices. The patients´ preferences enhance the efficacy.

PRS69

IDENTIFICATION OF DRY POWDER INHALER ATTRIBUTES, AND THEIR RELATIVE IMPORTANCE TO ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE PATIENTS, TO INFORM A DISCRETE CHOICE EXPERIMENT

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OBJECTIVES: To identify characteristics of dry powder inhalers (DPIs) considered important by asthma and *chronic obstructive pulmonary disease (COPD)* patients, in order to select attributes and attribute-levels for a discrete choice experiment. **METHODS:** Qualitative data was collected from a literature review performed to determine which inhaler attributes impact inhaler satisfaction and adherence among asthma and COPD patients using DPIs. Focus groups with asthma and COPD patients were conducted in France, with patients asked to cite and rate important features of their inhaler. Qualitative analysis of the transcripts was performed following International Society For Pharmacoeconomics and Outcomes Research (ISPOR) guidelines. **RESULTS:** Results of the literature review revealed no overall consensus on the importance of different inhaler attributes in relation to inhaler satisfaction and adherence across studies. The most frequently reported attributes were: overall ease-of-use, low inspiratory flow requirements, presence of a dosing feedback mechanism, ergonomics of the inhaler mouthpiece, ease with which the device can be kept hygienic and the ease with which the medicinal dose can be prepared. Four discussion groups were held, with thirty patients participating. Overall, the degree to which the inhaler can optimise treatment convenience appeared to be the most important attribute to patients. In agreement with results of the literature review, patients also rated the following inhaler attributes as being important: size of the dose counter, ability to keep the mouthpiece hygienic, ergonomics of the inhaler mouthpiece, presence of a dosing feedback mechanism, ease with which a dose can be prepared, low inspiratory flow requirements. **CONCLUSIONS:** Results of this study provide an insight inhaler attributes most valued by asthma and COPD patients. Patients described their ideal inhaler to be small, with an ergonomic mouthpiece and an easy to use dose preparation mechanism, and providing enough medicine for at least a month of treatment.

PRS70

SYMPTOM BURDEN AND HEALTH RELATED QUALITY OF LIFE IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS IN CLINICAL PRACTICE: INSIGHTS-IPF REGISTRY

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OBJECTIVES: We aimed to assess the symptom burden and health related quality of life in patients with idiopathic lung fibrosis. **METHODS:** Patients have been consecutively enrolled in an ongoing prospective non-interventional registry in Germany, investigating clinical characteristics, clinical management practices and quality of life. IPF diagnoses were in agreement with the international IPF guideline published in 2011. Clinical parameters and treatment practice were recorded by the physician. Patients filled out the EQ-5D-5L, St George's Respiratory Questionnaire (SGRQ), WHO-5 and the UCSD shortness of breath (SOB) scale. The time trade off (TTO) score was calculated for the EQ-5D. **RESULTS:** To date (04 June 2014), 421 patients with IPF have been enrolled in the registry (mean age 68.6±9.5; 77% male). The mean six-minute walk distance was 271±200, mean % of predicted forced vital capacity was 72±20 and the mean % predicted DLCO was 35±16. Patients were treated with oral steroids (22.1%, as monotherapy in 7.1%); N-acetylcysteine (34.8%), pirfenidone (47.2%), and long-term O2 therapy (34.4%). The physician rated the disease in 35.6% as stable, in 31.1% as slowly progressing and in 11.9% as rapidly progressing. One in four patients described their current state of health as at least good, and every fifth as poor. The mean EQ-5D TTO score was 0.8±0.2. 45% of the patients showed depressive symptoms based on the WHO-5. The mean SGRQ sum score was 47.7±20.1 describing difficulties with breathing in the previous 3 months. Higher EQ-5D TTO scores were significantly associated with a lower number of comorbid diseases (r=-0.31), higher 6-minute walk distance (r=0.20), higher FVC % pred (r=0.27), less depression (r=0.66) and lower SGRQ scores (r=-0.72). **CONCLUSIONS:** The IPF patients in this large registry had a more severe disease, a higher symptom burden and more compromised quality of life compared to recent randomised controlled trials.

PRS71

TRANSLATION AND LINGUISTIC VALIDATION OF TWO COPD SYMPTOM DIARIES (NICSI AND EMSCI) FOR USE IN 14 COUNTRIES

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OBJECTIVES: The Nighttime Symptoms of COPD Instrument (NiSCI) and Early Morning Symptoms of COPD Instrument (EMSCI) were developed to support treatment benefit endpoints in global clinical trials. Translations that were conceptually equivalent to the English source version and easily understood by the target country populations were required. The purpose of this study was to translate and assess conceptual equivalence of the NiSCI and EMSCI for use in 14 countries: Austria, Bulgaria, Canada, Czech Republic, France, Germany, Hungary, Italy, Lithuania, The Netherlands, Poland, South Africa, Spain, and United Kingdom. **METHODS:** The NiSCI and EMSCI were translated following ISPOR guidelines for linguistic validation of PRO measures (Wild et al., 2005) using the universal approach discussed in the second Task Force Report (Wild et al., 2009). The universal English, Spanish and French versions were previously translated (Eremenco et al., 2012). For the remaining languages, two forward translations by native translators, reconciliation of the forwards, one back-translation by an English-speaker fluent in the target language, and final reconciliation by a native speaking language coordinator were conducted for both measures. Harmonization was performed to ensure conceptual equivalence across languages. Interviews were conducted with five native-speaking COPD patients for each language/country combination. Interview data were analyzed to assess linguistic and cultural validity in each language and confirm conceptual equivalence. **RESULTS:** Mean age of the sample (N=80) was 60 years (range 41-83) and 54% were male. The translations were well understood and considered relevant, with patients raising only minor issues during interviews. Changes were made to the universal French (chest congestion), Hungarian (wheezing, chest congestion), Italian (chest congestion, moderately), and Lithuanian (instructions, wheezing, shortness of breath, experienced) following the patient interviews. **CONCLUSIONS:** All translated versions of the NiSCI and EMSCI in this study were found to be conceptually equivalent and acceptable for use in the 14 countries evaluated.

PRS72

TESTING E-PRO DEVICE USABILITY DURING THE TRANSLATION PROCESS: A CASE STUDY OF THE EXACT IN 7 COUNTRIES

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OBJECTIVES: Usability testing of electronic Patient-Reported Outcomes (ePRO) instruments is typically conducted during instrument development, in the language/country of origin. It has been suggested that usability testing also be performed during the translation process. It is unclear whether this additional step is necessary. In this study, usability testing was conducted as part of the linguistic validation process in Simplified Chinese (China), German (Germany), French (France), Russian (Russia), and Spanish (Universal, tested in Chile, Spain, and US) for the Exacerbations of Chronic obstructive pulmonary disease Tool (EXACT), an e-PRO developed and tested in English (US). **METHODS:** The translation process followed ISPOR guidelines (Wild et al., 2005). Cognitive interviews were conducted with 2-3 native-speaking COPD respondents per language/country combination in 2008. Subjects completed the EXACT in paper-pen screenshot format and were interviewed for translation validation. Subsequently they were instructed to use a PDA (Tungsten E2; CRF, Inc.) to complete the first 5 EXACT items and were interviewed regarding device usability. Interviewers rated subjects' ability to use the device. **RESULTS:** Subjects (N=20) were 45-84 years, 60% male, and 60% with secondary education or less. Most (n=18) had not used a PDA previously; all (n=20) reported